





National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods Interagency Coordinating Committee on the Validation

of Alternative Methods

National Institute of Environmental Health Sciences Research Triangle Park, NC

NICEATM and ICCVAM promote the scientific validation and regulatory acceptance of new and revised safety testing methods that:

- Reduce, refine, or replace the use of animals in testing
- Maintain and promote scientific quality and the protection of human health, animal health, and the environment

### NICEATM and ICCVAM do this by:

- Conducting and coordinating interagency reviews of new and revised toxicological test methods that apply to regulatory testing requirements
- Coordinating cross-agency issues on validation, acceptance, and national and international harmonization of new and revised toxicological and safety testing methods
- Ensuring that new and revised test methods are adequately validated to meet the needs of U.S. Federal agencies



The NICEATM-ICCVAM graphic symbolizes the important role of new and alternative toxicological methods in protecting and advancing the health of people, animals, and the environment.



### What is ICCVAM?

The Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM) is an interagency committee of the U.S. Government. ICCVAM's members represent the heads of 15 Federal regulatory and research agencies that require, use, or generate toxicological and safety testing information. This information is used to determine the safety or potential adverse health effects of chemicals and products to which workers and consumers may be exposed.

ICCVAM was formed in 1997 by the National Institute of Environmental Health Sciences (NIEHS), one of the National Institutes of Health. The ICCVAM Authorization Act of 2000 established ICCVAM as a permanent interagency committee of NIEHS under the National Toxicology Program Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM).

ICCVAM evaluates the scientific validity of new, revised, and alternative test methods with regulatory applicability, and forwards recommendations on their usefulness to Federal agencies for acceptance decisions. ICCVAM depends on stakeholders with appropriate capabilities and resources to carry out alternative test method research, development, and validation studies, and to submit the results to ICCVAM for evaluation. Test methods for which validation studies have been completed can be submitted to ICCVAM for final evaluation. ICCVAM also considers nominations of test methods for validation studies and test method issues from test method developers and the public.



#### What is NICEATM?

NICEATM provides scientific and operational support for ICCVAM. NICEATM works closely with ICCVAM to:

- Carry out test method evaluations
- · Sponsor test method validation studies
- Organize workshops and peer reviews
- Communicate with ICCVAM stakeholders

## What are the major duties of NICEATM and ICCVAM?

- Evaluate the scientific validity of new, revised, and alternative safety testing methods
- Provide recommendations on test method usefulness and limitations to U.S. Federal agencies
- Provide guidance on test method development and scientific validation
- Develop standardized protocols for new and revised test methods
- Identify reference substances for test method validation studies
- Develop performance standards for new test methods
- Collaborate with other national and international validation and test guideline organizations
- Communicate findings to regulatory agencies, the scientific community, and other stakeholders



# Test methods and approaches evaluated by ICCVAM include:

- Ocular toxicity
  - Bovine corneal opacity and permeability test
  - Cytosensor microphysiometer test
  - Isolated chicken eye test
  - Use of anesthetics, analgesics, humane endpoints in in vivo testing
- Acute oral toxicity
  - Up-and-down procedure
  - In vitro methods to set starting doses
- · Skin corrosivity and irritation
  - Corrositex®
  - EpiSkin™
  - EpiDerm™
  - SkinEthic™
  - Rat skin transcutaneous electrical resistance assay
- Skin sensitization
  - Local lymph node assay (LLNA)
  - Reduced LLNA
  - Non-radioisotopic LLNA protocols
- Endocrine disruption
  - In vitro estrogen receptor assays
  - *In vitro* androgen receptor assays
- Pyrogenicity
  - *In vitro* pyrogen tests

U.S. Federal regulatory agencies have approved or endorsed over 40 alternative test methods. ICCVAM and its member agency scientists have contributed to the review of all of these alternative methods.

### **ICCVAM Member Agencies**

(Member agencies are indicated in boldface)

- Consumer Product Safety Commission
- Department of Agriculture
- Department of Defense
- Department of Energy
- Department of Health and Human Services
  - Centers for Disease Control and Prevention
    - Agency for Toxic Substances and Disease Registry
    - National Institute for Occupational Safety and Health
  - Food and Drug Administration
  - National Institutes of Health
    - Office of the Director
    - National Cancer Institute
    - National Institute of Environmental Health Sciences
    - National Library of Medicine
- Department of the Interior
- Department of Labor
  - Occupational Safety and Health Administration
- Department of Transportation
- Environmental Protection Agency

More information about NICEATM and ICCVAM can be found on the NICEATM-ICCVAM web site:

### http://iccvam.niehs.nih.gov

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